IN THE UNITED STATES PATENT OFFICE

Applicants:	Paul A. Spence et al.
Serial No.:	10/695,380
Filed:	October 28, 2003
Art Unit:	3738
Examiner:	William H. Matthews
Conf. No.:	5321
Title:	HEART VALVE REPAIR APPARATUS AND METHODS
Atty Docket No.:	SPEN-03C

DECLARATION BY PAUL A. SPENCE, M.D. UNDER 37 C.F.R. § 1.132

I, PAUL A. SPENCE, hereby stated and declare the following:

I am named as an inventor in the above-captioned U.S. patent application (the '380 application) disclosing various forms of heart valve repair apparatus and methods of their use. My medical background, including my education, practical experience, publications and other relevant information are summarized in the attached Curriculum Vitae (Exhibit A).

As Exhibit B, I have attached a published diagram that accurately depicts the normal anatomy of the heart and, particularly, the mitral valve and adjacent structure of the heart. This diagram is consistent, for example, with Figs. 2 and 24 in the '380 patent application. In this regard, the mitral valve as shown in Exhibit B is located at the top of the left ventricle alongside the aortic valve. This is also shown in Fig. 2 of the '380 patent application. The outer wall of the heart is shown in Exhibit C adjacent to the posterior leaflet of the mitral valve, as is wall 12a in Fig. 2 The aortic valve is shown in Exhibit B on the opposite side of the mitral valve from the outer wall of the heart as also shown in Fig. 2 of the '380 patent application. In a similar manner, Fig. 24 of the '380 application shows the outer wall 12a of the heart, and the papillary muscle 24 which has

been severed in the same manner as shown in Fig. 2 of the '380 application. This is consistent with the anatomy of the heart as shown in Exhibit B and supports the amendments made to the specification and drawings to explicitly set forth which valve leaflet is the "anterior" leaflet and which valve leaflet is the "posterior" valve leaflet. As further shown in the top view of Exhibit C, the anterior leaflet and posterior leaflet (or cusps) meet at a junction which is generally curved as shown, for example, in Figs. 2 and 23 of the '380 patent application. The anterior leaflet is larger than the posterior leaflet and is on the concave side of the curved junction between the leaflets. For these reasons, the modifications made to Figs. 2 and 22-24 are fully consistent with the actual anatomy of the heart and one of ordinary skill in the art of mitral valve repair would readily understand that the changes made to the drawing figures and the corresponding changes to the written specification of the '380 application providing further explanation of the drawing figures are consistent and accurate depictions of actual heart anatomy as originally disclosed in the '380 application upon filing. From a review of, for example, Exhibit C and specifically the top view of the mitral valve in the lower diagram of Exhibit C, compared to the corresponding view of Fig. 23 from the '380 patent application, the mitral valve annulus is generally "D" shaped with a substantially straight portion extending along the anterior cusp or leaflet and a generally curvilinear portion extending along the posterior cusp or leaflet. This is also evident in Fig. 2 of the '380 patent application.

As shown in Fig. 24 of the '380 patent application, when a posterior portion of device 370 is formed in a nonplanar fashion and then affixed to the valve annulus posterior portion 376b as shown, the valve annulus will be forced into a position

according to the three-dimensional shape of the device 370. Thus, the vertical position of the annulus at that posterior location will be modified as compared to its natural position.

Further Declarant sayeth not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application or any patent issued thereon.

June 22 06
Date

Paul A. Spence

CURRICULUM VITAE
PAUL A. SPENCE, M.D.

Residential Address:	5818 Orion Road Louisville, Kentucky 40222	
Education:	Queen's University Faculty of Arts & Science Kingston Ontario, Canada	1974-1976
	Queen's University Medical School Kingston Ontario, Canada M.D. Degree	1976-1980
	University of Toronto Toronto, Ontario, Canada M.Sc. Degree	1983-1986
Internship:	McGill University Royal Victoria Hospital Montreal, Quebec, Canada	1980-1981
Residency:	University of Toronto General Surgery	1981-1986
	University of Toronto Cardiovascular & Thoracic Surgery	1986-1988
Academic Appointments:	Associate Professor of Surgery Department of Cardiac Surgery East Carolina University School of Medicine Greenville, North Carolina	1988-1992
	Associate Professor of Surgery Department of Surgery Division of Thoracic & Cardiovascular Surgery University of Louisville Louisville, Kentucky	1992-1999

	Professor of Surgery Department of Surgery Division of Thoracic & Cardiovascular Surgery University of Louisville Louisville, Kentucky	1999 -2000
	Clinical Professor Department of Surgery Division of Thoracic & Cardiovascular Surgery University of Louisville Louisville, Kentucky	2000 - 2004
Current Position:	Medical Device Investment Advisor Accelerated Technologies Inc Hackensack, NJ	
Medical Licenses:	North Carolina #32873 Kentucky #29237	1988 1992
Certifications:	American Board of Surgery American Board of Thoracic Surgery FRCS (C) General Surgery FRCS (C) Cardiovascular & Thoracic Surgery	1987 1989 1986 1988
Professional Organizations:	American Medical Association American College of Surgeons American College of Cardiology American Heart Association (Council on Circulation) Association for Academic Surgery Academy of Surgical Research Southern Thoracic Surgical Association Fellow of Royal College of Surgeons of Canada Sigma Xi European Association for Cardio-Thoracic Surgery Society of Thoracic Surgeons Southern Thoracic Surgical Society	
Hospital Committees:	**University of Louisville** Surgery Representative to Faculty Forum Physician Quality Improvement Committee	 1993-1995 1994-1995

	Jewish Hospital	
	Critical Care Committee	1993-1994
	Infectious Control Committee	1993-1994
	Heart & Lung Institute	1993-1994
	H/L Publication Advisory Committee	1997-1998
	Baptist East Hospital	
	Intensive Care Committees	1993-1996
Honors & Awards:	Tricolour Scholarship Queen's University	1974-1976
	Edgar Forrester Scholarship	1976-1980
	Murphy Memorial Scholarship	1976-1980
	N.F. Dupuis Scholarship	1976-1977
	Dr. Ernest C. Armstrong Prize	1977-1978
	Mosby Book Prize for Pathology	1977-1978
	W.G. Anglin Scholarship in Surgery	1978-1979
	Victor Lyall Goodwill Scholarship in Internal Medicine	1978-1979
	Rattray Scholarship in Ophthalmology	1978-1979
	W.W. Near & Susan Near Prize	1979-1980
	The Professor's Prize in Obstetrics & Gynecology	1979-1980
	Bryan George Blair Memorial Prize	1979-1980
	Neil Currie Polson Memorial Prize	1979-1980
	Frederick Boyd Prize	1979-1980
	Medical Research Council of Canada Fellowship	1983-1984
	Medical Research Council of Canada Fellowship	1984-1985
	Young Investigator Award - Canadian Cardiovascular Society	1984-1985
Journals:	*Current Surgery* - Executive Editor	1989-1992
	Current Surgery - International Editor	1989-Present
	Annals of Thoracic Surgery -Guest Reviewer	1990-Present
	Chest - Guest Reviewer	1991-Present
	Journal of Thoracic and Cardiovascular Surgery - Guest Reviewer	1990-Present

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1. **Spence PA,** Bayliss C, Peniston CM, Salerno TA: Right ventricular failure associated with left heart failure. *Cardiovascular Clinics,* 17:239-249, 1987.

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ABSTRACTS PUBLISHED

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12. Montgomery WD, **Spence PA**, Hansen SB, Gray AL, Santamore WP: A model to study arterial bypass graft vasoreactivity. *Journal of Investigative Surgery*, 74:362, 1994.

13. Montgomery WD, **Spence PA**, Sinai K, Santamore WP: Mechanism of spasm in gastroepiploic artery bypass grafts. *Clinical Research*, 42(3):475A, 1994.

14. Zeri RS, Lust LM, **Spence PA**, Hopson SZ, Sun YS, Otaki M, Jolly SR, Mehta PM, Chitwood WR: The effects of chronic competitive flow from a fully patient coronary artery on thoracic artery grafts. Ann of Thorac Surg 57: 45-50, 1994.

15. Driver AG, Kukoly C, **Spence PA**, Chitwood WR, Mustafa SJ: Pericardial fluid adenosine in ischemic and valvular heart disease. Chest 107:346, 1995.

16. BhaskerRao B, VanHimbergen D, Edmonds HL, Jaber Saad, Ali AT, Pagni S, Koenig S, **Spence PA:** Evidence for Improved Cerebral Function After Minimally Invasive Bypass Surgery. Jour Card Surg 13, (1):27-31, 1998.

17. Singer I, Dawn Buddhadeb, Calzada N, **Spence PA**: Atrial Fibrillation: A Delayed Presentation of Traumatic Tricuspid Valve Incompetence. *Cardiology* Vol 89#4, May 1998.

18. Prabhune A, Sehic A, Spence, PA, Church T, Edmonds, HL. "Cerebral Oximetry Provides Early Warning of Oxygen Delivery Failure During Cardiopulmonary Bypass". Journal of Cardiothoracic and Vascular Anesthesia. Vol 16, 2 (April) 204-206, 2002.

BOOK CHAPTERS

1. Peniston CM, **Spence PA,** Archer D, Jabr AK, David TE, Salerno TA: Does the size of the prosthesis affect global ventricular function following mitral valve replacement. Proceeding of the World Conference on Open Heart Surgery, 1985.

2. **Spence PA,** Peniston CM, Weisel RE, Easdown J, Jaber AK, Yap V, Salerno TA: Right heart failure during left heart bypass: the role of pulmonary artery balloon counterpulsation. Proceeding of the World Conference on Open Heart Surgery, 1985.

3. Peniston CM, El-Dalati H, **Spence PA,** Salerno TA: The significance of arterial cooling and electrical inactivity in myocardial protection. Chapter 26 in *Myocardial Protection in Cardiac Surgery*, ed. Arthur J. Roberts, Dekker, 1987.

4. Wittnich C, **Spence PA,** Salerno TA: Pulmonary artery balloon counterpulsation for right heart failure. *Counterpulse*, 1991.

5. Lattouf OM, Jabr AK, **Spence PA**. Pitfalls in warm oxygenated blood cardioplegia. *Warm Heart Surgery*. Arnold, 1995.

6. Cerrito P., Koenig SC., **Spence PA**. Automated classification procedures and neural network models to predict the level of anastomotic stenosis in off-pump CABG surgery. Chapter 8: In Intraoperative graft patency verification in cardiac and vascular surgery. Futura Publishing Company, Armonk, NY., May 2001.

EDITORIALS, SPECIAL ARTICLES AND BOOK REVIEWS

1. **Spence PA,**: New approaches to aortic valve surgery [review]. Current Surg 51:359-60, 1994.

2. **Spence PA:** Editorial: A careful operation. *Current Surgery,* 48:131, 1991.

3. **Spence PA:** Editorial: Medical new from around the world. *Current Surgery,* 47:56, 1991.

4. **Spence PA:** Editorial: Further thoughts on laparoscopic intervention. *Current Surgery,* 48:631, 1991.

5. **Spence PA,** Lust RM, Ruiz V: Operative strategy and techniques. *State of the Art Reviews*, 5:3, 1991.

ARTICLES SUBMITTED

1. Otaki M, Lust RM, Norton TO, Sun YS, **Spence PA,** Chitwood WR Jr: Extracardiac adjustment of mitral chordae replacement. Submitted *Journal of Surgical Research.*

2. Montgomery WD, **Spence PA,** Riordan CJ, Storey JH, Santamore WP: An evaluation of the duration of effectiveness of vasodilators on intact porcine ITA and GEA bypass grafts. Submitted *European Journal of Cardiothoracic Surgery.*

3. Cerrito P, Koenig SC, VanHimbergen DJ, Jaber S, Ewert DL, Bhasker-Rao B, Spence PA: Neural Network Pattern Recognition Analysis of Graft Flow Characteristics Improves Intra-operative Anastomotic Error Detection in Minimally Invasive CABG. Eur J. Cardiothoracic Surg.

PRESENTATIONS

1. **Spence PA,** Morin JE, Katz M: Plasmapheresis in Preparation for Thymectomy. *Surgical Grand Rounds*. Royal Victoria Hospital, McGill University, Montreal, November 1982.

2. **Spence PA,** Mathews PE, Kanna R, Oreopoulos DG: When Should Laparotomy be Performed for Peritonitis in Chronic Ambulatory Peritoneal Dialysis Patients. *Annual Assembly of General Surgeons*, University of Toronto, May 1984.

3. **Spence PA,** Easdown J, Jabr AK, Weisel RD, Salerno TA: The Hemodynamic Effects and Mechanism of Action of Pulmonary Artery Balloon Counterpulsation in the Treatment of Right Ventricular Failure During Left Heart Bypass. *Gallie Day Competition*, University of Toronto, May 1984.

4. **Spence PA,** Easdown J, Jabr AK, Salerno TA: Pulmonary Artery Balloon Counterpulsation for the Failing Right Ventricle. *European Society of Cardiology*, Dusseldorf, Germany, July 1984.

5. **Spence PA,** Jabr AK, Yap V, Salerno TA: Limitations on the Capacity of the Systemic Circulation to Maintain Cardiac Output Without the Participation of the Right Ventricle. *American Physiological Society Annual Fall Meeting*, Lexington, Kentucky, August 1984.

6. Salerno TA **, Spence PA**: Right Heart Assist During Left Heart Bypass. *Strikeman Visiting Professor Meeting*, McGill University, Montreal PQ, May 1984.

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11. **Spence PA,** Weisel RD, Jabr AK, Yap V, Salerno TA: Is Atrial Function Affected by Conventional Cardioplegic Arrest? *Annual Meeting of the Association for Academic Surgery*, San Antonio, Texas, November 1984.

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14. **Spence PA,** Jabr AK, Bayliss C, Peniston CM, Weisel RD, Salerno TA: Maintenance of the Cardiac Output Without Participation of the Right Ventricle - The Importance of Pulmonary Vascular Resistance. *Symposium of the Right Heart*, Phoenix, Arizona, April 1985.

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ACADEMIC PRESENTATIONS

1. Acquired Heart Disease. Junior Students, University of Louisville.

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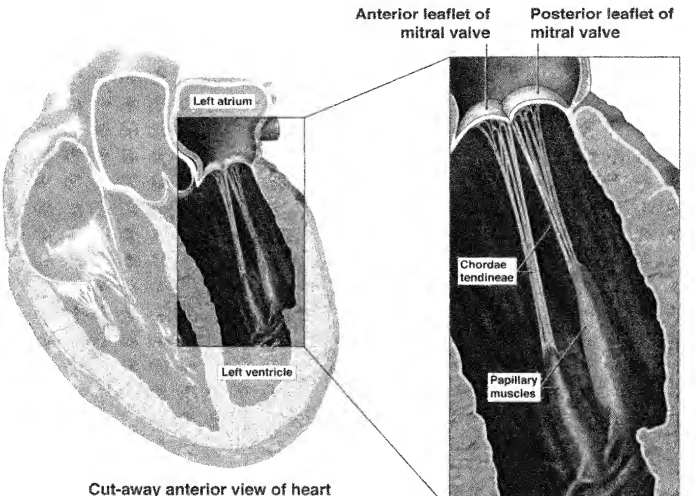
Normal Anatomy of the Mitral (Bicuspid) Valve of the Heart



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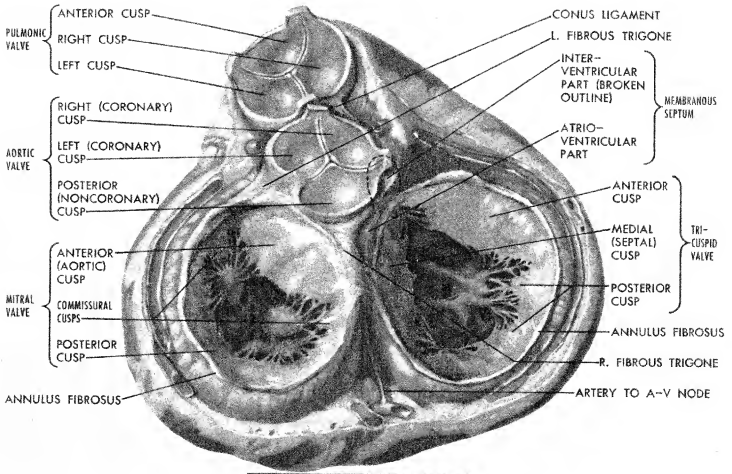

THE HEART IN DIASTOLE: VIEWED FROM BASE WITH ATRIA REMOVED

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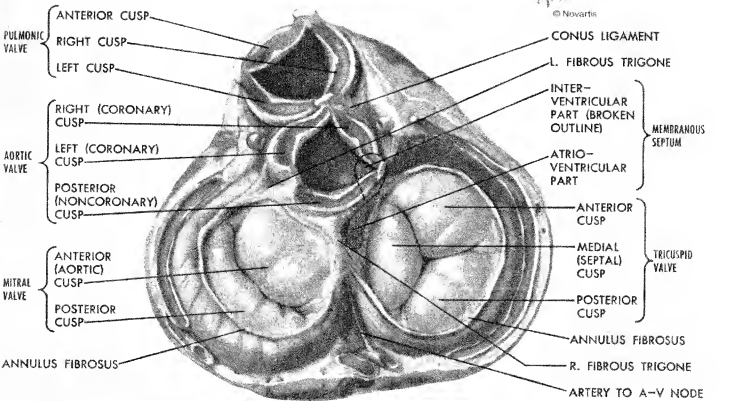

THE HEART IN SYSTOLE: VIEWED FROM BASE WITH ATRIA REMOVED

Exhibit C